EXHIBIT DD

Clinical Expert Report

Gynecare Gynemesh* PS

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***Trademark**

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A. MANUFACTURER'S STATEMENT ON THE CLINICAL DATA USED TO AFFIX CE-MARK:

The following clinical evaluation is based on the assessment of the risks and the benefits, associated with use of the device through:

- ✓ A compilation of relevant scientific literature that is currently available, as well as a written report containing a critical evaluation of this compilation.

B. DEVICE DESCRIPTION & BACKGROUND:

GYNECARE GYNEMESH* PS Non-absorbable PROLENE* Soft Mesh is a specially designed supportive, soft, synthetic mesh that is placed into the pelvis and is used to restore pelvic support. GYNECARE GYNEMESH PS use is an option for the surgical treatment of the early onset of pelvic organ prolapse and was the first polypropylene mesh support material for female pelvic floor repair to be introduced into the market.

GYNECARE GYNEMESH* PS is constructed of knitted filaments of extruded polypropylene identical in composition to PROLENE* Polypropylene Suture, Non-absorbable Surgical Sutures, U.S.P. (ETHICON, INC.). This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use.

GYNECARE GYNEMESH* PS is a Type 1 mesh and it affords excellent strength, durability and surgical adaptability along with sufficient porosity for necessary tissue ingrowth. Blue PROLENE monofilament fiber strands have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE mesh. GYNECARE GYNEMESH PS is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaption to various stresses encountered in the body.

GYNECARE GYNEMESH* PS is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

It is recommended that sutures, staples or other appropriate fixation devices be placed at least 6.5 mm (1/4") from edge of the mesh. Some surgeons prefer to suture into position an uncut section of mesh that is considerably larger than the defect. When the margin sutures have all been placed, the extra mesh is trimmed away.

GYNECARE GYNEMESH* PS is available in single packets as sterile, clear sheets with blue stripes. The mesh is sterilized by ethylene oxide. The mesh is not to be re-sterilized

Animal studies show that implantation of PROLENE* mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

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GYNECARE GYNEMESH* PS Contraindications, Warnings/Precautions/Interactions, Adverse Reactions and Storage Instructions include the following:

Contraindications

When this mesh is used in infants, children, pregnant women or women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.

Warnings/precautions/interactions

- Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing GYNECARE GYNEMESH* PS for pelvic reconstruction.
- Acceptable surgical practices should be followed for the management of infected or contaminated wounds.
- The use of GYNECARE GYNEMESH* PS in contaminated wounds should be used with the understanding that subsequent infection may require additional surgical procedures such as removal of the mesh.

Adverse reactions

Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction.

Storage

Recommended storage conditions: below 25°C, away from moisture and direct heat. Do not use after expiry date.

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Since the introduction of GYNECARE GYNEMESH* PS in 2002-2003, there have been no changes to the design of the mesh or packaging materials. There have been several changes to the packaging graphics and labeling as necessitated by marketing of the mesh in additional countries around the world. A new product code was added in 2005 offering a larger size (GPSLX - 10 inch x10 inch) mesh.[1]

C. LITERATURE REVIEW:

I. Introduction

Under the direction of and in cooperation with the Ethicon Women's Health and Urology World-Wide Director of Medical Affairs, a focused team within Women's Health and Urology conducted a Clinical Literature Review addressing the clinical use of synthetic grafts in female pelvic floor applications. Specifically, this review produced a safety analysis of synthetic mesh grafts used in vaginal urogenital prolapse repair techniques.

The primary objective of the review was to provide the most current, documented clinical experience as insight into the following:

- The scientific background of tissue changes and wound healing in prolapse patients
- Issues or concerns regarding the use of the implant materials used to reinforce repairs to include: infection, seroma formation, shrinkage, erosion and fistula formation
- Recommended standards of care from well regarded sources to include: Status of any Cochrane reviews or similar critical examinations of the literature regarding synthetic mesh use

II. Search Strategy

- Include gynecologic and urogynecologic surgery applications
- Examine literature from 2000 through 2009
- Comprehensive examination, by including all relevant terms that cover:
    - Medical specialty (i.e., Gynecologic, Gynecology, Urologic, Urology, and General Surgery)
    - Female pelvic anatomical references and surgical procedures
    - Major forms of the term, synthetic mesh and or graft

III. Search Databases and Summary Findings

- International Urogynecology Association (IUGA) annual meeting abstracts 2001 to 2008
- 2009 IUGA meeting abstracts pertaining to synthetic mesh "kits"
- Supplemented by: PubMed, Cochrane Review, NICE searches (with the elimination of duplications due to subsequent publication of IUGA meeting abstracts

- Summary of search results:
  - 194 IUGA abstracts 2001 to 2008
  - 44 IUGA 2009 abstracts
  - 10 relative articles (safety and complication rates) PubMed (2000 to 2009)
  - 1 Cochrane Database of Systematic Reviews review
  - 6 National Institute for Health and Clinical Excellence Guidance documents

IV. Selection Criteria

- Gynecologic and Urogynecologic applications
- Randomized controlled trials, non-randomized comparative studies, registry reports, case series and case reports as the objective was to assess safety and very rare complications that might only be indicated in smaller studies and case reports
- Substantially based on the compilation of data from the IUGA congress reports, versus PubMed cited literature entirely, in order to capture as many patients as possible through the combination of all smaller series reported through the series of IUGA congresses, known to focus on these type of procedures more than any other international body or association.

V. Findings for Synthetic Mesh Grafts Used in Vaginal Urogenital Prolapse Repair

a) Overall Findings:

The overall success rates for anterior vaginal wall prolapse surgery using synthetic grafts is higher than when performing traditional techniques with gross success in more than 86% compared to 72% respectively after a variable, but short term follow up. Mean reported erosion rates using synthetic grafts in the anterior compartment range from 2.6% – 6.8% and from 0 to 12.1% and from 4.7 to 14.4% in the posterior and middle compartment respectively. Other complications are rare, with the most frequently reported being bladder perforations ranging from a mean of 1.8% to 3.8% of cases in studies reporting upon this complication.

b) General Conclusion:

Scientific evidence demonstrating a low recurrence rate of prolapse after novel needle suspension techniques with mesh is accumulating. This improved outcome compared to traditional repairs to treat urogenital prolapse is partially offset by an additional morbidity related to the use of mesh grafts. This is almost solely related to mesh erosion. Chronic or life threatening complications are considered rare. Hemorrhagic incidences and de novo dyspareunia appear to be less than in techniques involving traditional vaginal repairs or abdominal sacrocolpopexies.

c) Detailed Findings:

- There are an increasing number of reviews in the literature suggesting that the insertion of a prosthetic mesh in a tension-free fashion via the vagina in patients suffering from symptomatic urogenital prolapse will reduce the chance of recurrence in certain indications. [Jia, Feiner, Sung, De Ridder]
  - Similarly, the Maher, et al study first published within the Cochrane Database of Systematic Reviews in October 2004 and recently updated, April 2010, concluded: "the use of mesh or graft inlays at the time of anterior vaginal wall repair reduces the risk of recurrent anterior wall prolapse, on examination. Posterior vaginal wall repair may be better than transanal repair in the management of rectoceles in terms of recurrence of prolapse."
- Looking at the global success rates of graft reinforced vaginal prolapse procedures, there was noted a higher success rate when compared to traditional repairs. For the two mesh kits most reported upon, the mean success rates were 93 and 87% respectively, after a short mean follow up time of 8 and 6 months. For both procedures a range of successes between 80 and 100% could be found; traditional repairs, reported upon in the traditional repair arms of comparative studies, on the contrary, only reported success rates between 62 and 88%, with a mean of 74%. It must be noted that the follow up time for this group of patients was significantly longer, however, at a mean of 18 months.
- Similar successes could be found for treatment of the middle compartment with success rates of 87% (85-88%) for Prolift and 93% (88-100%) for Apogee procedures. These data seem to correspond with the data obtained from PubMed cited articles wherein the successes range between 81 and 95%. All these studies report on a follow-up shorter than or equal to one year only. The longest reported outcome in the IUGA series relates to a tension free positioning of Gynemesh by Letouzey et al in 2008 on 54 patients. Follow up amounted to 79 months (6+ years) and they reported a success of 80% and an erosion rate of 10%.
- The National Institute for Health and Clinical Evidence (NICE) organization which independently advises the National Health Service (NHS) of the United Kingdom has provided guidance based on clinical reviews it has conducted. These reviews in both qualitative and substantive elements parallel the findings of the Women's Health and Urology Clinical Literature Review team. NICE guidance indicates the following:
  - Regarding the vaginal vault, the evidence suggests that surgical repair of vaginal wall prolapse using mesh may be more efficacious than traditional surgical repair of vaginal wall prolapse without mesh. Both efficacy and safety vary with different types of mesh, and the data on efficacy in the long term are limited in quantity. There is a risk of complications that can cause significant morbidity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. (IPG 267 - 6/08) Additionally, related to sacrocolpopexy, current evidence on the safety and efficacy of sacrocolpopexy using mesh for vaginal vault prolapse

repair appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance and audit. (IPG 283 - 1/09) However, there is inadequate evidence on the efficacy and safety of infracoccygeal sacropexy using mesh for vaginal vault prolapse repair and only clinicians specialized in the management of pelvic organ prolapse should conduct such a procedure. (IPG 281 - 1/09)

- Related to the uterine cavity, there is inadequate evidence on the efficacy and safety of: infracoccygeal sacropexy using mesh for uterine prolapse repair (280) - 1/09, insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair (282) - 1/09, and sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair (284) -1/09. For these procedures it is recommended that only clinicians specialized in the management of pelvic organ prolapse do them. And, proper notification of governing bodies should be carried out as well as ensuring patients fully understand the uncertainty about the procedures safety, in particular, mesh erosion.

- The emergence of a new morbidity accompanying the commercialization of mesh repair kits for urogenital prolapse has stirred a lively debate between mesh adopters and antagonists. [Nygaard, IJUG 2007, Isom-Batz G, Exp Rev Med Dev 2007, Swift, IJUG 2007, Paraiso JMIG 2008]
- On October 20th, 2008, the United States Food and Drug Administration (FDA) issued a Public Health Notification entitled: "Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence". Over three years, the FDA had received over 1,000 reports from nine surgical mesh manufacturers of complications that were associated with surgical mesh devices used to repair pelvic organ prolapse and stress urinary incontinence. They stated in their notification that "although rare, these complications can have serious consequences".
- In considering the specific complications, the following summarize the results of this review.
  - Mesh Erosion of pelvic organ tissues
    - Erosions are, by incidence, the single most important complication that the use of synthetic graft reinforcements has introduced in pelvic floor surgery. Erosion rates range from 3.2 to 19.3% depending on the compartment receiving the graft reinforcement and the particular mesh employed.
    - The study by Abdel Fattah et al in The BJOG of 2008, also noted higher mesh excision rates in total procedures. They did not reveal a trend to higher erosion rates in the posterior than in the anterior compartment. This difference can probably be explained by the fact that more mesh is used when performing a repair of the middle compartment. The effect can, hence, be explained by the fact that erosion rate correlates to the bulk of mesh utilized in the repair. These erosion rates are higher when compared to erosion rates reported after laparoscopic sacrocolpopexies, with a rate reported by Claerhout et al after 1 year in 132 patients of 4.5%. [Claerhout]

- A comprehensive review by Nygaard reported 70 erosions in 2178 patients (3.4%). [Nygaard 2004] The review of Diwadkar corroborated these findings with a weighted average for erosion after sacral colpopexy of 2.2% and for mesh kits of 5.8%. The Nygaard review concluded that combining a hysterectomy with a sacrocopopexy increased the risk of erosion fourfold. The same effect was observed in a retrospective analysis of 684 TVM procedures using Gynemesh Prolene Soft, between 2002 and 2004, as described by Caquant et al.. [Caquant] They reported an 11.5% mesh exposure rate when a hysterectomy was done concommitently as opposed to 4.7% without removing the uterus.

- Many of these erosions are asymptomatic and a large proportion of them can be easily managed by local estrogen application and/or partial excision during an office visit. The study by Elmer reported a fairly high mesh exposure rate, however, only a surgical re-intervention rate to excise the exposed mesh in 2.8%. [Elmer 08] Similarly, Hinoul reported a 10.4% exposure rate and a 4.3% intervention rate to excise the mesh partially. [Hinoul]

– Vesicovaginal or rectovaginal fistula

- There are very few abstracts reporting on the development of a fistula, despite the large number of patients reported upon in these congress abstracts. It is not impossible, however unlikely, that this severe complication would not have been reported upon by these authors. One fistula has been reported upon in 1,695 Prolift patients upon whom complications were reported (erosions excepted), 1 in 670 TVM patients, and 2 in 1,611 unspecified polypropylene meshes. The retrospective review of 684 TVM procedures revealed two vesicovaginal fistulas and one rectovaginal fistula (0.44%). [Caquant]

– Material Perforations

- The incidence of bladder perforations though small appeared to receive more attention in 2009 abstracts. Reported occurrences ranged from 2.8% to 7.7%. Comparative methods were not used in any of these reports, but qualitative conclusions suggested these were associated more closely with the underlying surgical approach and tissue exposure than with the use of mesh for the POP repair.

– Perioperative visceral lesions

- These lesions are not uncommon. Most of them are located at the level of the bladder with an overall incidence rate for Prolift procedures around 2.2%. There are fewer reports on Perigee reporting this complication, this may be explained by the fact that the most distal anterior needle tends to turn less deep in the pelvis during a Perigee procedure, probably allowing for a less extensive dissection.

- Rectal lesions are far less common. Only one was described in 937 Apogee patients and 1 in 854 IVS patients. Two PubMed cited studies in Scandinavia reported 4/248 and subsequently 1/252 rectal lesions following Prolift procedures. [Altman, Elmer] These rates seem high in both studies compared to other reports. A rectal examination is recommended after every posterior kit procedure to identify any perforations of the rectum preoperatively. Surgeons are advised to abandon mesh placement (posteriorly) when this occurs.
- The overall visceral injury rates compare favorably to the rates encountered when performing a sacrocolpopexy with a average rates for its occurrence of 1.7% and 1.1% after sacrocolpopexy and mesh kit respectively. [Diwadkar]

– Hematoma

- Hematomas are commonly reported in the IUGA series in approximately 3% of mesh kit procedures. Rarely are transfusions required. As vascular injuries can be life threatening, despite their rare occurrence, 4 case reports following Prolift have been published. Two of them were self limiting, one required embolization of the internal iliac artery and the other was an injury of the internal iliac vein which required embolization and packing. In the PubMed literature the series of Abdel Fattah included two significant vascular injuries: one to the right pudendal artery requiring suturing and 5 units of packed cells and one lesion to the uterine artery requiring embolization and transfusion with 4 units of packed cells. No other reports of life threatening vascular injuries could be identified. Here too, the comparison to traditional repairs and sacrocolpopexies is favorable; based on Dindawar's review the weighted averages are 2.8%, 1.6% and 1.1%, for traditional repairs, sacrocolpopexy and mesh kits respectively.

– Dyspareunia

- Dyspareunia is a more problematic outcome measure to assess than might be expect. Not all authors account for the actual number of sexually active patients in their study. Secondly some patients may not be sexually active before surgery due to the prolapse and others may have become sexually inactive after surgery due to the procedure (certainly when assessing short term follow up <6months) or unrelated factors (partner's impotence, lack of desire,...). A study specifically addressing the dyspareunia issue after Prolift by Lowman in the AJOG of 2008 identified a high de novo dyspareunia rate of almost 17% after Prolift. [Lowman] Surprisingly, studies after sacrocolpopexy yielded de novo dyspareunia rates as high as 15 and 19 %. [Handa, Claerhout] A report by a tertiary referral center on 22 patients treated for complications following all types of mesh surgeries to treat prolapse over a period of almost 4 years stated that the most common symptom in 10/22 patients was dyspareunia. [Blandon 2009]

- Traditional repairs are associated with 19% of de novo dyspareunia rates [Weber] and associating a levator ani placation would increase the incidence to 27%. [Kahn] Performing a midline fascial placation or a discrete fascial repair in a comparative study yielded similar dyspareunia rates of 14 and 19%. [Abramov] Finally, the sacrospinous ligament fixation has been associated with de novo dyspareunia rates as high as 36%. [Maher]

– Pain Syndrome

- The incidence in the PubMed literature varies widely from 1.2% to 6.4%. A review of reoperations for complications following mesh surgery in a tertiary referral centre identified 13 patients. The primary complaint in 9 of these 13 patients (69%) was vaginal pain; 85% suffered from mesh exposure. Two contributing factors identified by this team for these two complications were mesh folding, which was identified in 9 of 13 patients during surgical exploration, and mesh shrinkage. As normal urinary, sexual and defecatory functions require a compliant vagina, excessive stiffness can lead to dyspareunia, defecatory and urinary dysfunction. [Margulies 2008] Also of note in this article on 13 complications was that the median time from mesh surgery to presentation was 8 months (1-16m) and that a median of 2 additional procedures were required to achieve acceptable results. A similar report by a tertiary referral center on 22 patients treated for complications following all types of mesh surgeries to treat prolapse over a period of almost 4 years stated symptoms other than dyspareunia included chronic vaginal drainage in nine patients, pain not related to intercourse in 7. [Blandon 2009] In 14 patients, pain could be elicited on vaginal palpation.
- One of their most important findings is that only 14% of patients were referred by the original surgeon, suggesting a lack of awareness of these complications by the original treating physician and the potential for underreporting of the rate and extent of these complications due to non-respondent/volunteer bias. The authors, however, fail to recognize that 22 cases for many different types of procedures is not a very high number of patients considering the magnitude and authority of the tertiary referral centre reporting upon this series. Finally, this article also commented upon the fact that urogynecologists were the original surgeon in only 9% of the cases. This supports the notion that surgical technique may have contributed to the development of these complications and emphasizes the need for specialized training.

- In summary, notwithstanding the attention clinicians, the U.S. FDA, the Cochrane Database of Systematic Reviews and NICE have given to the question of complications associated with synthetic mesh used in pelvic organ prolapse surgery, the complication rate is considered "rare" and for in instances can be minimized through specialized training (Urogynecology) and meticulous surgical technique. Furthermore, when complications are encountered thorough awareness and immediate action also lessens severity. Additionally, based on the experiences cited by numerous researchers, the more serious complications (sans mesh erosion) occur no more frequently with mesh than in the traditional prolapse treatment techniques. And, finally, mesh use is associated with higher prolapse cure success rates, at least in the follow-up periods that are currently available.

D. LITERATURE REVIEW CONCLUSION STATEMENT:

The above data, taken together with any available pre-clinical data, are sufficient to demonstrate compliance with the essential requirements covering safety and performance of GYNECARE GYNEMESH* PS under normal conditions of use. No additional clinical data is required.

E. COMPLAINT / ADVERSE EVENT REVIEW:

I. Internal complaint review

a. GYNECARE GYNEMESH* PS is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect. The typical environment for its use is within the boundaries of the sterile field of the operating theater of a hospital.

Complaints for the period 2/2007 thru 1/2010 [2] are summarized in the following table:

COMPLAINT SUMMARY:	
Gynemesh PS:	
• Infection	2
• Intra - Op Complication	5
• Mesh Tears - during implantation	1
• Mesh Tears - handling	1
• Post-Procedure Complication	29
• Vaginal Exposure	9
Sub-Total	47
Packaging:	
• Difficult to open	1
• Open Seal	1
Sub-Total	2
Grand Total	49

The corresponding volume of units distributed for this same time period equaled 49, 059[3] producing an overall compliant rate of .0010%

II. MAUDE Review

A search of the Manufacturer and User Facility Device Experience (MAUDE) Database maintained by the U. S. Food and Drug Administration produced the following for the period January 2000 through March 2010.

One Hundred Twenty-five (125) records of reported adverse events are on file from 2004 through March 2010.

- One Hundred Twenty-four (124) reported "injuries"
  - In the most recent annual period, 2009, Sixteen (16) injuries reported related to erosion with various forms of intervention, including: estrogen treatment and excision
  - In 2005, the year with the greatest number of annual reported instances, representing 55% (56 instances) of the total, the unique events were as follows:
    - 12 UTI (judged unrelated to the mesh itself)
    - 11 exposures and excisions (predominately partial excisions)
    - 7 Infections
    - 4 hematoma (judged unrelated to mesh)
    - 3 each: exposures and POP recurrence
    - 2 each: material perforations (related to surgical technique), Urinary incontinence, erosion, and pain
    - 1 each: cystocele, and ureter obstruction
  - In 2007, the year with the second highest number of annual reported instances, representing 17% (21 instances) of the total, the unique events were as follows:
    - 5 Dysperunia
    - 4 Exposures and excisions
    - 2 POP recurrence
    - 1 each: erosion, bladder perforation, ureter obstruction
    - 5 unspecified
- One (1) reported "death", October 19, 2007
  - Unrelated to mesh implant – surgeon opinion stated "death due to multiple organ failure attributable to sepsis from perforated bowel which occurred during surgery."

III. Internal versus MAUDE Database Complaint Review Experience

Internal complaint review records, as indicated above, by comparison to the MAUDE Database information compare in an as expected manner for the period January 2007 through January 2010. The MAUDE review, however, extended to the original 510 k FDA approval date of the device, January 2002. For this reason the MAUDE review identifies and examines additional complaint instances. These additional instances, however, do not significantly differ from the more recent experiences with the exception of overall number, particularly in 2005 (an early year of the devices existence) and the one reported death (in 2007) which was not attributable to the device.

IV. Product Recall

Based on the available information at the date of this report there have been no recalls of this device.

F. RISK / BENEFIT ANALYSIS:

In accordance with established Ethicon Inc Research & Development, Quality Engineering, Quality Assurance, and Medical Affairs departmental and company procedures/processes *(including the adoption of ISO 14971 [supporting procedural documents are available as required])*, an in-depth analysis of the GYNECARE GYNEMESH* PS complaints and investigation outcomes has been conducted. The analysis produces an overall residual risk score and an assessment of overall residual risk level attributable to these devices.

The underlying factors of harm and hazard and their associated severity of harm and estimated frequency of harm together with complaints data and number of devices distributed are used to arrive at the overall risk score and the assessed overall residual risk level. Please see Table I and Table II below for a summary of these factors.

Table I
Harms/Hazards Summary Table [4]

Harm*	Severity of Harm*	Hazard*	Frequency of Harm Rating‡
Unintended Tissue Reaction	9	• Unintended scarring • Occult Incontinence	4
Blood Loss	10	• Dissection error	4
Internal Organ Damage	10	• Dissection error • Mesh erosion/exposure	6
Exposure – GI	10	• Dissection error	6
Exposure – Vaginal	10	• Poor vagina incision closure • Dissection error	4
Erosion - UT	10	• Dissection error	8
Fistula Formation	10	• Dissection error	4
Infection	10	• Use of non sterile device	4
Failure of Treatment	9	• Recurrent vaginal wall prolapse	6

** As defined per ISO 14971[5]*

‡ Value "Estimated Harm" determined by contents of following, Table II

Table II
Harms Estimation Table

Ranking of Frequency (F)	Attribute Description	Variable Description*
0	Extremely Remote	X ≤ 1/100,000 (or ≤10 dfm**)
2	Remote	X ≤ 1/50,000 (or ≤20 dfm)
4	Unlikely	X ≤ 1/10,000 (or ≤100 dfm)
6	Low	X ≤ 1/5,000 (or ≤200 dfm)
8	Rare	X ≤ 1/1,000 (or ≤1000 dfm)
10	More than Rare	X >1/1000 (or >1000 dfm)
*	*Per number of devices or procedures as dictated by nature of device.*	
**	*Defects per one million devices or procedures as dictated by the device.*	

The analysis outcomes for Gynecare Gynemesh PS are as follows:

		GYNECARE Gynemesh* PS[6]
Overall Residual Risk Score		**46**
Overall Residual Risk Level		**High**

According to the procedures and practices consistent with regulatory guidelines and company policy, the above scores and assessments indicate the need for a complete Risk/Benefit analysis. As a result of this process and a thorough review of all other pertinent information, including: a detailed clinical literature review as provided in Section C of this report and the complaint reviews (internal and MAUDE Database) as provided in Section E, the overall residual risk associated with Gynecare Gynemesh is considered acceptable in view of well documented benefits/patient outcomes.

# # #

G. REFERENCES:

The following pages contain the specific citations for the references and footnotes within this report. The actual reference documents are available on request. They have been handled in this manner in order to keep the report to a reasonable length.

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Other documents supporting the CER:

[1] Design Change History for GPS and Prolift

[2] Ethicon document: RMR-0000052_GyneMesh_PS-A

[3] Ethicon document: RMR-0000052_GyneMesh_PS-A

[4] Ethicon document: RMR-0000052_GyneMesh_PS-A

[5] Ethicon document: PR602-003-r.15

[6] Ethicon document: RMR-0000052_GyneMesh_PS-A

